

Serial No. 10/530,464
Arty. Doc. No. 10442-004

In the Claims:

Please amend the claims as follows:

1. (previously presented) A method for determining, between two times, a change in a level of concentration of an analyte present in a source, comprising:

providing multiple unitary test devices, each unitary test device including a plurality of regions, each region responsive at a different sensitivity level to indicate presence of the analyte in the source;

bringing a first sample from the source into contact with a first of the unitary test devices at a first time to induce, at the first time, a visually observable response in one or more regions of the first test device based on the source containing a minimum level of analyte concentration; and

subsequently bringing a second and different sample from the same source into contact with a second of the unitary test devices at a second time to induce at the second time, a visually observable response in one or more regions of the second test device based on the source containing a minimum level of analyte concentration; and

comparing a visually observable response induced in the first test device at the first time directly with a visually observable response induced in the second test device at the second time to provide information about a change in the level of analyte concentration between the two times.

2 – 9. (canceled)

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10. (currently amended) A method for monitoring changes in analyte level of a source, comprising:

defining multiple measurably distinguishable sensitivity levels each indicative of a different amount of analyte in the source;

providing first and second test units,

the first test unit including a first region thereon responsive to the presence of analyte in the source at a first of the sensitivity levels; and a second region responsive to presence of analyte in the source at a second of the sensitivity levels measurably distinguishable from the first of the sensitivity levels,

the second test unit including a first region thereon responsive to the presence of analyte in the source at the first of the sensitivity levels and a second region responsive to presence of analyte in the source at the a second of the sensitivity levels;

providing a first sample from the source at a first time;

bringing the first sample into contact with the first unit to allow the first region thereon to provide an indication as to whether analyte is present in the sample at at least the first of the sensitivity levels;

providing a second sample from the source at a second time subsequent to providing the first sample; and

bringing the second sample into contact with the second unit to allow the first and second regions thereon to provide an indication as to whether analyte is present in the second sample at at least one of the first and second sensitivity levels,

wherein a difference between a visually observable response induced in the first test device at the first time and a visually observable response induced in the second test device at the second time can provide information about a change in the level of analyte concentration between the two times. wherein indications of presence of analyte in the first sample and indications of presence of analyte in the second sample provide evidence as to whether there has been a change in analyte level between the first time and the second time.

11. (previously presented) The method of claim 10 wherein the first unit includes a second region responsive to presence of the second level of analyte and the step of bringing the first

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sample into contact with the first unit includes allowing thesaid second region to indicate whether analyte is present in the sample at at least the second of the sensitivity levels.

12. (canceled previously presented) The method of claim 10 wherein the first unit includes a second region responsive to presence of one measurably distinguishable sensitivity level different than the first of the sensitivity levels and the step of bringing the first sample into contact with the first unit includes allowing said second region to indicate whether analyte is present in the sample at at least said one sensitivity level different than the first of the sensitivity levels.

13. (canceled previously presented) The method of claim 12 wherein said one measurably distinguishable sensitivity level different than the first of the sensitivity levels is substantially the same as the second of the sensitivity levels.

14. (canceled previously presented) The method of claim 10 wherein the second test unit includes a second region thereon responsive to the presence of analyte in the source at the first of the sensitivity levels.

15. (previously presented) The method of claim 10 wherein the step of providing the first test unit includes forming thereon at least three regions each responsive to the presence of analyte in the source at a different one of the multiple measurably distinguishable sensitivity levels.

16. (previously presented) The method of claim 15 wherein the step of providing the second test unit includes forming thereon at least three regions each responsive to the presence of analyte in the source at a different one of the multiple measurably distinguishable sensitivity levels.

17. (canceled previously presented) The method of claim 16 wherein the steps of providing the first and second test units are performed such that at least one of the three regions of the first unit and one of the three regions of the second unit are responsive to the presence of analyte in the source at substantially the same sensitivity level.

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18. (previously presented) The method of claim 16 wherein each of the regions of the first unit is responsive to substantially the same level of analyte as one of the regions of the second unit.

19. (currently amended) The method of claim 10 wherein the step of defining multiple measurably distinguishable sensitivity levels each indicative of a different amount of analyte in the source is accomplished by forming at least the first and second regions.

20. (previously presented) A method for monitoring changes in analyte level of a source, comprising:

providing two or more test units each including multiple regions thereon, each region in each unit responsive to the presence of an analyte in the source at a sensitivity level measurably distinguishable from another region in the same test unit;

bringing a first sample from the source into contact with a first of the units to allow one or more of the regions thereon to indicate whether the analyte is present in the sample at at least one of the levels; and

on an occasion subsequent to providing the first sample, bringing a second sample from the source into contact with a second of the units to allow one or more of the regions thereon to indicate whether the analyte is present in the second sample at at least one of the levels,

wherein different indications of presence of analyte in the first and second samples provide evidence as to whether there has been a change in analyte level subsequent to providing the first sample.

21. (previously presented) The method of claim 20 wherein the step of providing one of the test units includes adhesively mounting the multiple regions on a substrate.

22 - 24. (canceled)

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25. (previously presented) A method for determining a change in a level of concentration of an analyte present in a source, comprising:

providing multiple unitary test devices, each unitary test device including a plurality of regions, each region responsive at a different sensitivity level to indicate presence of the analyte in the source without being determinative of a numerical concentration of the analyte in the source;

on a first occasion, bringing a sample from the source into contact with a first of the unitary test devices to induce a visually observable response thereto in one or more regions of the first test device when the source contains a predetermined minimum level of analyte concentration;

subsequently, on a second occasion, bringing a different sample from the same source into contact with a second of the unitary test devices to induce a visually observable response thereto in one or more regions of the second unitary test device when the source contains a predetermined minimum level of analyte concentration; and

comparing a visually observable response induced in the first test device directly with a visually observable response induced in the second test device to provide information about a change in the level of analyte concentration without requiring determination of analyte concentration in the source on either occasion.

26. (previously presented) The method of claim 25 wherein the first and second test devices are configured to indicate presence of chorionic gonadotrophin as the analyte, and wherein the second occasion is at least one day after the first occasion, the method indicating whether analyte concentration has increased between the first and second occasions.

27. (previously presented) The method of claim 25 wherein the first and second test devices are configured to indicate presence of chorionic gonadotrophin as the analyte, and wherein the second occasion is at least 72 hours after the first occasion, the method indicating whether analyte concentration has doubled between the first and second occasions.

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28. (previously presented) The method of claim 10 wherein the step of providing the first and second test units includes forming the first and second units separate and apart from one another.

29. (previously presented) The method of claim 20 wherein the step of providing two or more test units includes forming the test units separate and apart from one another.